

REMARKS

Applicant has read and considered the Office Action mailed March 17, 2008. Applicant would like, at the outset, to thank the Examiner for the indication of allowable subject-matter for claims 1-13. The claims are not amended in the present amendment. Claims 1-20 are pending.

In the Office Action, the drawings were objected to because the reference number 32 is not shown on the drawings. The Examiner's attention is drawn to Figure 6, which clearly shows the corrective positive mold 32.

When reviewing the corresponding text in the specification, it appears that a typographical error had been introduced at page 11, line 19 regarding reference number 32 and this has been corrected by the present amendment. Applicant asserts that the objection to the drawings has been overcome and requests that the objection be withdrawn,

Claims 14 and 15 were rejected under 35 U.S.C. § 102(b) as being anticipated by Jalbert et al. (U.S. 4,513,518). Claim 14 is independent and claim 15 depends on claim 14.

Claim 14 is directed to a custom made foot orthosis for engagement inside footwear and for conformingly fitting against a bottom surface of a foot of a person for correcting anatomic biomechanical deficiencies of the foot and ensuing body deficiencies of the person. The custom made foot orthosis includes a thermoformed flexible top layer made of a first moldable synthetic rubber material, the top layer having a shape for conformingly fitting against the bottom surface of the foot.

The orthosis also includes a thermoformed flexible reinforcement core layer made of a moldable core material that is molded onto the top layer. The core layer has a posterior end aligned with a mid anterior plantar prominence of a calcaneus bone of the foot, and an anterior end aligned near metatarsalphalangeal joints defined between metatarsal bones and phalange bones of the foot.

The orthosis also includes a thermoformed flexible bottom layer made of a second moldable synthetic rubber material that is molded onto the top layer and the core layer, the core layer being more rigid than the top and bottom layers; whereby when the foot orthosis is used by the person, the top and bottom layers cushion walking impacts on a calcaneus spine of the calcaneus bone of the foot, while the core layer transmits the walking impacts to a foot surface extending from the mid anterior planter prominence of the calcaneus bone of the foot to near the metatarsalphalangeal joints.

In can be appreciated that the expression "thermoformed" in the context of the present invention means that each of the layers is malleable under heat and when heated, espouses the shape of the bottom surface of the foot of the person. Moreover, the expression "custom made" means that each foot orthosis is made for a specific user. It does not come in standard sizes and in fact, cannot be made in series since each foot orthosis is custom made for the specific foot of the user requiring such an orthosis.

Jalbert et al. is directed to a shoe inner sole. A first major fundamental difference between the subject-matter of the present application and the inner sole disclosed by Jalbert et al. is the issue of customization versus standard insoles. Indeed, as mentioned previously, the orthosis of the present invention is molded to provide a conforming fit to the foot of a user. Each orthosis is made individually and is individually molded to the foot of the user. In contrast, Jalbert et al. is directed to mass production of insoles which come in standard sizes. This can be gleaned from the Background of the Invention, column 1, lines 5-29, discussing prior art directed to separately-formed innersoles that are often loosely inserted into athletic and other shoes. There is no teaching or suggestion there that these insoles are individualized for a specific user.

Moreover, at column 2, lines 16 and following, Jalbert et al. describes the innersole 10 having an upper layer 12 of microcell polyurethane foam bonded by an adhesive to a lower layer of cross-linked polyethylene foam. Jalbert et al. continues at line 27 by stating that "if other polyurethane foams are used, they should preferably have a compressive load deflection characteristic in the range of 5 to 25 psi when compressed 25% of original thickness at a 1/inch/minute rate." Clearly, these are not the values that the foot of a user can produce when molding an individual orthosis. Starting at line 46, Jalbert et al. states:

"To prevent breakdown of the polyurethane during thermoforming, the polyethylene is separately heated in an oven and bonded to the polyurethane just prior to insertion in the compression press."

Applicant asserts that a "compression press" has absolutely nothing to do with the foot of a user in a far gentler thermoforming process as contemplated by the present invention.

"The breakdown temperature of the polyurethane (i.e. the maximum temperature to which it can be exposed for short intervals) is 250° F., which is less than the roughly 275° F. temperature to which the polyethylene must be elevated for thermoforming."

Here, the temperature as it has been described cannot be produced in any manner by the foot of a user when thermoforming the various layers to have them conform to the foot of the user. Jalbert further states:

"While the polyethylene is being heated, the polyurethane is prepared for bonding by applying adhesive and drying the adhesive under heat lamps. The heated polyethylene and glue-bearing polyurethane are then bonded together and placed in a compression molding press. The heel piece, to which the same adhesive has been applied, is separately placed in the press. Water is used to cool the press and thereby reduce thermoforming time. After thermoforming, the inner soles are die cut to final size."

These passages clearly teach an industrial process in which the insoles are made in batches, more likely in standard sizes, and shipped to retail outlets for individual insertion into shoes. This process is far removed from the customization process taught in the present invention. Therefore, the "custom made foot orthosis" taught and recited in claim 14 cannot be anticipated by Jalbert et al.

Additionally, Jalbert et al. is not obvious under 35 U.S.C. §103(a) since Jalbert et al. does not teach or even remotely suggest customizing the insole to the individual needs of a user. The mass production of Jalbert et al. teaches away from the present invention. The cited passages from Jalbert et al. also lead a skilled person to conclude that the thermal forming step is not the step to actually mold individual layers, but rather to heat the adhesive so that proper bonding can occur between the various layers. It is thus respectfully requested that the 35 U.S.C. §103(a) rejection be withdrawn in view of the above comments.

Claim 16 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Jalbert et al. in view of Mardix et al. Claims 18 and 19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jalbert et al. in view of Goldman (U.S. 5,775,332).

In both rejections, there is no teaching or suggestion in Jalbert that the insole could be modified to become a custom made foot orthosis as claimed in the present invention. Mardix et al. teaches an extremely soft material which, by repeated use of the material, eventually conforms to the form of the foot, but in no way does it provide corrective benefits such as the orthosis of the present invention. Goldman and Mardix fail to remedy the deficiencies of Jalbert et al.

Moreover, with respect to claims 18 and 19, the Office Action states that Goldman teaches in Figure 3 a feed back sensor device and that it would have been obvious to one having ordinary skill in the art that the additional layer in the heel cushion layer as taught by Goldman could be incorporated into the device disclosed by Jalbert et al. Since Jalbert et al. cannot be used as a primary reference as discussed above, the combination of Jalbert et al. and Goldman is therefore improper.

In view of the above, Applicants respectfully request that the rejection be withdrawn and a Notice of Allowance be issued. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

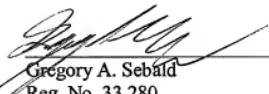
Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

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